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Special 510(k) Summary
This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

Submitter:

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Establishment Registration Number: 3008592715

Contact:

Martha Garay
Regulatory Affairs & Quality Assurance Manager
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Date of Summary: October 14, 2013

Predicate 510(k) Number: K130380 – OrthoSensor Knee Balancer

Special 510(k) Number: K131767

Trade/Proprietary: OrthoSensor Knee Balancer (Trade / Proprietary names = OrthoSensor VERASENSE™ Knee System).

Classification Name: Intraoperative Orthopedic Joint Assessment Aid

Product Code: ONN

Device Classification: Class II (21 CFR 882.4560)

Intended Use: For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE™ Knee System is sterile, for single patient use.

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Device Description: OrthoSensor VERASENSE™ Knee System provides a means to dynamically balance the knee during knee replacement surgery intra-operatively. The system includes an instrumented trial tibial insert comprising an array of load sensors that measure the forces applied on its surface and angular positional information (such as alignment, varus/valgus, posterior and anterior slope positioning, etc.) after insertion into the space between the tibia and the femur.

Description of Changes to the Device: The reason for this proposed special 510(k) submission is to include a modification to the package label (specifically the outer label) to reflect the use of the OrthoSensor VERASENSE™ Knee System with the Biomet Vanguard Knee System (K113550). In addition to this change on labeling, this submission also covers the changes to the device surface contours and dimensions (specific to the condylar surface of the Biomet Vanguard Knee System), as well as the addition of a new color of Polycarbonate (for Makrolon Rx 1851).

Completion of Design Control Activities:
The modifications to the Orthosensor VERASENSE™ Knee System were evaluated under design controls, and met the same performance criteria as the predicate device. Dimensional changes were implemented to meet customer needs (BIOMET), with new sizes and catalog numbers. The design control process was followed and the risk analysis method used to determine assess risks associated with these changes was Failure Mode Effects Analysis (FMEA), which has been updated appropriately.

Substantial Equivalence:
The proposed updated submission has the same intended use as the predicate and same technological characteristics that do not raise different types of questions of safety and effectiveness. The proposed updated submission is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 28, 2014

OrthoSensor, Incorporated
Ms. Martha Garay
Regulatory Affairs & Quality Assurance Manager
1855 Griffin Road, Suite A-310
Dania Beach, Florida 33004

Re: K131767
Trade/Device Name: OrthoSensor VERASENSE™ Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ONN
Dated: September 6, 2013
Received: September 9, 2013

Dear Ms. Garay:

This letter corrects our substantially equivalent letter of September 6, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ORTHOSENSOR

K131767

Indications for Use Statement

Device Name: OrthoSensor Knee Balancer (Proprietary name=VERASENSE™ Knee System).

Indications for Use: For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE™ Knee System is sterile, for single patient use.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __NO__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices